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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,521	06/27/2000	Gloria M. Coruzzi	5914-083-999	5147

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.
09/605,521Applicant(s)
Coruzzi et alExaminer
Jane ZaraArt Unit
1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 14, 15, and 21-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 14, 15, and 26 is/are rejected.
- 7) ☒ Claim(s) 21-25 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

This Office action is in response to the communication filed April 2, 2003, Paper No. 11.

Claims 8-10, 14, 15, 21-26 are pending in the instant application.

Any rejections not repeated in this Office action are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed April 2, 2003 is sufficient to overcome the rejection of claims 21-25 based upon lacking scope of enablement for the generation of transgenic plants with enhanced growth phenotypes comprising ectopically expressing glutamate 2-oxoglutarate aminotransferase.

Response to Arguments and Amendments

Claims 8-10, 14, 15 and 26 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed for the reasons of record set forth in the Office action mailed December 2, 2002, Paper No. 9.

Applicant's arguments filed April 2, 2003 have been fully considered but they are not persuasive. Applicants argue that the claimed invention is enabled for its entire scope and that the unpredictability of an experimental result is not to be equated with undue experimentation. Contrary to Applicants' assertions, the ability to predict the phenotypes claimed for transgenic plants comprising appropriate isoforms of ectopically overexpressed aspartate aminotransferase,

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glutamate dehydrogenase or asparaginase requires undue experimentation and is not simply a matter of not predicting the results for a single experiment. No correlation has been found between the overexpression of any of these enzymes in transgenic plants, whereby increased fruit and seed yields, greater total plant nitrogen content, amino acid content, vegetative tissue or growth rates are observed. The generation of transduced *Arabidopsis thaliana* plants with GS, AS or GOGAT isoforms described in the instant disclosure is not representative of transgenic plants exhibiting increased fruit and seed yields, greater total plant nitrogen content, amino acid content, vegetative tissue or growth rates following their transduction with appropriate isoforms of aspartate aminotransferase, glutamate dehydrogenase or asparaginase. The communication provided April 9, 2002 describes nitrogen assimilation in plants as a process requiring the coordinated actions of GS and GOGAT enzymes... And eventually involving the biosynthesis of aspartate and asparagine, and further states that different isoenzymes in the pathway of nitrogen assimilation may play different roles depending on both environmental conditions and tissue types. Determining the proper isozymes for the various enzymes claimed, and determining the proper conditions for generating transgenic plants with the claimed phenotypes would therefore require undue experimentation beyond that described in the instant disclosure.

Applicants argue that the evidence disclosed in the declaration filed April 2, 2003 regarding the generation of transduced *Arabidopsis* expressing ectopic GOGAT is enabling for the broad scope of the claims, including the generation of transgenic plants expressing appropriate isoforms of aspartate aminotransferase, glutamate dehydrogenase or asparaginase. Contrary to

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Applicants' assertions, the successful transduction into Arabidopsis of GOGAT is not representative of the generation of transgenic plants with increased fruit and seed yields, greater total plant nitrogen content, amino acid content, vegetative tissue or growth rates following ectopically expressed aspartate aminotransferase, glutamate dehydrogenase or asparaginase. The ability to ectopically express a particular enzyme isoform involved in nitrogen assimilation does not enable the generation of transgenic plants ectopically expressing a totally different enzyme.

Applicants argue that transformed plants could predictably be achieved using a gene encoding aspartate aminotransferase, glutamate dehydrogenase or asparaginase and which plants have increased growth phenotype. Contrary to Applicants' assertions, the proper isozymes that are involved in nitrogen assimilation and anabolic reactions in plants must be empirically identified following their ectopic expression in plants. The identification and appropriate expression of aspartate aminotransferase, glutamate dehydrogenase or asparaginase in plants, whereby the desired phenotypes are obtained, requires experimentation beyond that provided in the instant disclosure.

Applicants argue that inoperative embodiments do not necessarily render a claimed invention non-enabled. This is true, but the ability to generate transgenic plants with enhanced growth phenotypes involved unspecified and untested isoforms of various enzymes is not a non-working embodiment, it is unpredictable and must be tested empirically. Therefore, the rejection for lacking enablement over the broad scope is maintained not because of non-working embodiments existing in the claims, but because the ability to predict the appropriate activity and

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generation of phenotypes in plants comprising the ectopic expression of uncharacterized enzymes in transgenic plants requires experimentation beyond that provided in the instant disclosure.

Allowable Subject Matter

Claims 21-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

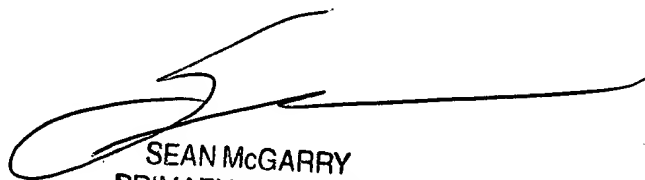
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Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

June 11, 2003


SEAN MCGARRY
PRIMARY EXAMINER
1635